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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20031215

Application Number: 09/185,607
Filing Date: 11/4/98
Appellant(s): LEUNG ET AL

Stephen Maebius
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/15/03.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The brief does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. Therefore, it is presumed that there are none. The Board, however, may exercise its discretion to require an explicit statement as to the existence of any related appeals and interferences.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct, however the rejection of claims 19, 21-27, 29, 53-55 under 103 as obvious based on Shih et al (US 5,057313) taken in view of Leung et al (Int J. Cancer 60:534-538, 1995) and Qu et al (Glycobiology 7:803-809, 1997) has been dropped in view of arguments presented.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 19, 21-27, 29, 53-55 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 1, 4-14, 16-18, 38, 41, 44, and 47 are rejected under 35 U.S.C. 112, first paragraph. This rejection was set forth in the Office Action mailed 12/7/00 and contained multiple enablement issues of which many have been overcome. The part of the rejection that is still applicable is whether "ketone derivative of a saccharide or biosynthetic saccharide precursor" is enabled.

Briefly, the rejection is set forth because of the broadness of the phrases and that the claims encompass adding any molecule, which can even be a carbon atom from any molecule, that is introduced into the biosynthetic pathway of saccharides.

Response to Arguments

Appellants on page 9-11 of the Brief argue that there is a very limited number of saccharides that are used in glycosylation and have previously cited from Stryer, Biochemistry, Figures 14-18. The reference is stated to show the formulae of saccharides commonly found in oligosaccharide units of glycoproteins and include β-L-

fucose, β-D-glucose, β-D-galactose, sialic acid, etc. Therefore the Brief states that the scope of the term "saccharide" is both well defined and fully enabled. Appellants state on page 10 of the Brief that the term "biosynthetic saccharide precursor" is similarly enabled and that there are a limited number of saccharide precursors and the specification mentions mannosamine and this compound is one of a limited group of well-known saccharide precursors. The Brief continues and states that the phrase when considured within the context of glycosylated antibodies as presently claimed defines a discrete and identifiable class of compounds and not a myriad of compounds as alleged by the examiner (see page 10-11 of Brief).

The factors to be considured in determining whether undue experimentation is required are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). The majority of these factors are addressed below.

A. The Breadth of the claims:

The claims encompass any compound that results in a ketone derivative of a saccharide by the biosynthetic pathway of saccharides. In response to arguments that saccharides are defined and enabled, while it is not unclear what a saccharide is or that Stryer clearly describes saccharide units, what is at issue is the broadness of the compounds encompassed by the phrase "ketone derivative of a saccharide or biosynthetic sachcharide precursor" and what these compounds are which are to be added to the culture medium to result in a ketone of a saccharide. The phase

encompasses any molecule, which can even be a carbon atom from any molecule, that is introduced into the biosynthetic pathway of saccharides.

B. The amount of direction or guidance disclosed in the specification:

The specification teaches only ManLev and N-levulinoyl fucose as compounds that are incorporated into the glycosylation site in the antibody (see page 7 of specification). Additionally, the specification cites Mahal et al (Science 276:1125, 1997) for teaching ManLev also. Therefore, the only compounds disclosed in the specification are only ManLev and N-levulinoyl fucose.

C. The state of the prior art:

The prior art of record does not describe the myriad of compounds encompassed by the phase. The Brief on page 10 cites Yarema et al as teaching ManLev. Additionally the prior art of Stryer only teaches saccharides and not the myriad of biosynthetic saccharide precursors encompassed by the claims. Therefore, it appears that only ManLev and N-levulinoyl fucose are enabled.

D. The presence or absence of working examples:

The specification describes one example (Example 5) which only uses ManLev as the compound added to the culture medium for production of the glycosylated antibody having a reactive ketone.

E. The quantity of experimentation which would be required in order to practice the invention as claimed:

The claims encompass any compound added to the culture medium that results in a ketone derivative of a saccharide. One skill in the art would have to first determine which compounds can be used or result through biosynthetic processes in a ketone derivative. The specification does not teach any assay or methods to determine such.

Appellants argue in the Brief on page 11 that a skilled artisan clearly would be appraised that a "ketone derivative" refers to compounds in which a ketone functionality is introduced on a saccharide or biosynthetic saccharide precursor, for example, as an N-acyl group such as levulinoyl, and would be able to introduce such ketone functionality using nothing more than the level of ordinary skill in organic synthesis. In response to this argument, it is well known what a ketone is and also in the context of a ketone of a saccharide. What is at issue is that again the response only point to N-acyl of levulinoyl and no other compounds. It is not just determining how to synthesize a ketone of a saccharide that is at issue, it is what compounds can be used or added to the culture medium that results in a ketone derivative and such compounds except ManLev or N-levulinoyl fucose are not enabled.

2. Claims 8-14, 16-18, 19, 21-27, 29, 44, 46, 47, 49, 53-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8, 16, 19, 22, 30, 44, 47, 53-55 have been amended to recite "wherein the reactive ketone group is not introduced by oxidation". The response filed 11/5/02 states that support for the amendment is found at page 2 of the specification and the response cites the teachings of Leung et al "Leung II" as support and the response states that the present invention provides glycosylated antibodies that do not require oxidation (see pages 6-7 of response). The response has been carefully considured but is deemed not to be persuasive. While the specification teaches a method that does not require oxidation the cited work by Leung II is just prior art and background and the specification does not show support for excluding oxidation of the sugar by chemical methods. Applicant is required to provide specific support for the limitation or remove it from the claims.

Response to Arguments

Appellants argue on page 16 of the Brief that the examiner admits that "while the specification teaches a method that does not require oxidation, the cited work of Leung II is just prior art and background and the specification does not show support for

excluding oxidation of the sugar by chemical methods" "He appears to discount his understanding that this is the case" and "A skilled artisan [the examiner?] has recognized that appellants were in procession of glycosylated antibodies and antibody fragments that possess 'a reactive ketone group that is not introduced by oxidation" (see page 17).

In response to this argument, the work cited for support is again in the background section and there is nothing in the specification disclosing that the ketone is not introduced by oxidation. The entire section on pages 1-3 cite numerous example of prior art, but the specification does not disclose that the methods of the invention do not require oxidation or the antibodies are not produce by oxidation to produce a ketone. In fact the summary of the invention on page 3-5 does not exclude oxidation in any method. The summary states "it is, therefore, an object of the present invention to provide antibodies and antibody fragments that can be readily conjugated at specific sites to yield immunoreactive immunoconjugates" (see page 3-4) and "In accordance with other embodiments, the present invention provides a glycosylated antibody or antigen-binding antibody fragment having a reactive ketone group on the glycosylated site" (see page 5). Therefore, the specification does not exclude oxidation of the glycosylated antibodies in order to produce the antibody with the ketone reactive site.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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December 11, 2003

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